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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,807	05/17/2006	Magali Faure	112701-700	3407

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BELL, BOYD & LLOYD LLP
P.O. Box 1135
CHICAGO, IL 60690

EXAMINER	
NIEBAUER, RONALD T	

ART UNIT	PAPER NUMBER
1654	

NOTIFICATION DATE	DELIVERY MODE
03/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/564,807	FAURE ET AL.	
	Examiner	Art Unit	
	RONALD T. NIEBAUER	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *6-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I (claims 1-5,15) and the species of hydroxyl amino acid in the reply filed on 1/12/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that 'hydroxyl amino acid' is not technically a species since there is more than one amino acid with a hydroxyl group. In order to advance prosecution the application has been examined based on the current species election (i.e. hydroxyl amino acid).

Claims 6-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/12/08.

Claims 1-5,15 are under consideration.

Information Disclosure Statement

The information disclosure statement filed 11/3/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. In the instant case, only the abstract of foreign patent document 1181244 has been provided. As such, a full copy of the foreign document 1181244 has

not been provided. Unless document 1181244 is only one page and only contains an abstract, the IDS fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document.

Claim Objections

Claim 4 is objected to because of the following informalities:

Claim 4 recites 'free amino acids' twice within the same group.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5,15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Shahjee et al. (J. Biosci. v27 Sept 2002 515-520) teach that L-amino acids are naturally occurring (title) and predominantly found in all living organisms (page 515 last sentence). Claims 1-5,15 of the instant invention are drawn to compositions of naturally occurring amino acids.

Jacobson et al. (US 6,166,181) teach that a naturally occurring protein, the human A2b adenosine receptor (claim 1, column 33-35) contains the amino acids Serine (SEQ ID NO:23

position 21), Threonine (SEQ ID NO:23 position 5), and Cysteine (SEQ ID NO:23 position 29) for example. Claim 4 for example is drawn to compositions of 'entire proteins'.

Clark et al.,(http://www.hortnet.co.nz/publications/science/smart.htm (accessed Feb 2008) originally published in NZ Kiwifruit Dec 1994) teach that free amino acids are present in kiwifruit (page 1 2nd paragraph). Clark teach that amino acids such as serine and threonine are present in kiwifruit, apple, and banana (Table 1 page 3).

There is no indication that the compositions of the current invention have been isolated or removed from a naturally occurring environment. In fact claim 4 states that the compositions can include free amino acids and proteins from natural sources. The claimed subject matter therefore reads on a product of nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5,15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 states that the amino acid is in an amount effective to favor the growth and the balance of bacterial microbiota. Claim 5 states 'amounts' such as 0.07 to 0.35 g/kg body weight/day. However, from such a description the metes and bounds of the claimed amounts are unclear. The 'amounts' recited in claim 5 are dosage ratios, not specific amounts. As such, the

composition is not drawn to specific amounts and is variable depending on the body weight for example.

Claim 1 and 2, for example, recite that the composition comprises amino acids and their derivatives. However, no specific examples are given of derivatives nor would one recognize what the applicant is referring to. In particular, it is unclear what modifications can be made to the amino acid in order it to render it a derivative.

Claim 4 recites that the form is selected from a group of possibilities. However, the possibilities are unclear. For example, 'entire proteins from natural source synthetically peptides' is unclear. As claimed, it appears that applicant is calling a synthetic peptide a natural peptide. However, a synthetic peptide by definition is not natural. Further, 'amino acid hydrolysates of different source of animal or plant proteins' is unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4,15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus …") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a

substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

In the instant case, the claims are drawn to compositions comprising amino acids and their derivatives (claim 1 and dependent claims).

(1) Level of skill and knowledge in the art:

The level of skill in the art is high.

(2) Partial structure:

Claim 1 and 2, for example, recite that the composition comprises amino acids and their derivatives. However, no specific examples are given of derivatives nor would one recognize

what the applicant is referring to. In particular, it is unclear what modifications can be made to the amino acid in order to render it a derivative. Since no specifics are provided there could be any amount of derivitization resulting in any number of derivatives. Hence, there is substantial variability in the genus. However, the examples in the specification recite specific amino acids such as serine and threonine. These examples are not representative of the genus of derivatives. Since there are a substantial variety of derivatives possible within the genus, the examples do not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

Claim 1 and dependent claims recite that the composition is for restoring or promoting a healthy and optimal microbiota ecosystem. However, no direction is given as to which derivatives would have such function. There is no known or disclosed correlation between structure and function. Further, there is no common sequence or common core taught for the derivatives.

(5) Method of making the claimed invention:

The specification (specifically example 1) describes particular compositions. However, the examples in the specification are not drawn to 'derivatives'. The specification fails to describe the synthesis of a representative number of derivatives.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1-4,15 is/are broad and generic, with respect to all possible derivatives encompassed by the claims.

The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the derivatives. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of amino acids identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of derivatives embraced by the claims.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Vinnars (US 5,310,768).

Vinnars teach nutritional compositions (columns 3 lines 6-10) specifically compositions comprising free amino acids such as serine, threonine, and cysteine (column 3-4 specifically the table at the bottom of column 3) thus meeting the limitations of claims 1-4,15 of the instant invention. In particular Vinnars teach the specific amino acid type as recited in claims 2,5 (serine or threonine), the form as recited in claim 4 (free amino acid), and a formulation as in claims 3,15 (a nutritional). Vinnars specifically teach 2-10 g dry component/l of serine, and 2-8 g dry component/l of threonine (column 3 bottom table) and teach that 1l of the amino acid solution is given to a person weighing 70kg (column 3 lines 47-50). As such the dosages are 0.0285-0.14 g/kg body weight /day of serine, and 0.0285-0.11 g/kg body weight/day of threonine. The specific amounts recited in the table of column 4 (6g/l of serine and 4.2 g/l of threonine) correspond to 0.0857 g/kg body weight /day of serine and 0.06 g/kg body weight /day of threonine thus meeting the limitations of claim 5 of the instant invention.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

Claims 1-5,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballevre et al. (US 2001/0031723) (as cited previously).

Ballevre teach nutritional compositions containing an effective amount of threonine (abstract, claim 28,claim 40 for example) meeting the limitations of claims 1-4,15 of the instant invention. In particular Ballevre teach the specific amino acid type as recited in claims 2,5 (threonine), the form as recited in claim 4 (free amino acid), and a formulation as in claims 3,15 (a nutritional). Ballevre teach specific amounts of threonine (claims 29-31,33-34, Figure 1 for example). Ballevre teach 0.07-0.2 g threonine/kg body weight/day (section 0042) thus meeting the limitations of claim 5.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

Claims 1-5,15 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,159,615 (as cited in the IDS).

GB 1,159,615 teach nutritional dietary compositions as described in Tables I-III (claim 12 page 12). The tables reveal that the compositions include the free amino acids threonine and serine for example meeting the limitations of claims 1-4,15 of the instant invention. In particular GB 1,159,615 teach the specific amino acid type as recited in claims 2,5 (serine or threonine), the form as recited in claim 4 (free amino acid), and a formulation as in claims 3,15 (a

nutritional). GB 1,159,615 teach specific amounts of the amino acids in Table I page 3 for example meeting the limitations of claim 5 as currently interpreted.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

Claims 1-5,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al.,(http://www.hortnet.co.nz/publications/science/smart.htm (accessed Feb 2008) originally published in NZ Kiwifruit Dec 1994).

Clark teach that free amino acids are present in kiwifruit (page 1 2nd paragraph). Clark teach that amino acids such as serine and threonine are present in kiwifruit, apple, and banana at specific amounts (Table 1 page 3) meeting the limitations of claims 1-4,15 of the instant invention. In particular Clark teach the specific amino acid type as recited in claims 2,5 (serine or threonine), the form as recited in claim 4 (free amino acid), and a formulation as in claims 3,15 (a fooood). Clark teach specific amounts of the amino acids in (Table 1 page 3) for example meeting the limitations of claim 5 as currently interpreted.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-25 of U.S. Patent No. 5,863,906 ('906).

Although the conflicting claims are not identical, they are not patentably distinct from each other.

'906 teach a nutritional composition comprising amino acids such as threonine and serine (claim 14) thus meting the limitations of claims 1-4,15 of the instant invention. '906 teach specific amounts of the amino acids (claim 20) meeting the limitations of claim 5 as currently interpreted.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

Claims 1-5,15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 5,756,481 ('481). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'481 compositions comprising amino acids such as cysteine and threonine (claims 1,14), specifically as a nutritional (claim 19) thus meting the limitations of claims 1-4,15 of the instant invention. '481 teach specific amounts of the amino acids (claim 14) meeting the limitations of claim 5 as currently interpreted.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

Claims 1-5,15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 10/595,419 ('419) and Derynck et al. (US 4,886,747). Although the conflicting claims are not identical, they are not patentably distinct from each other.

'419 teach nutritional compositions comprising TGF-beta (claim 1).

Derynck et al. (column 1 lines 58-60) teach that TGF-beta includes the amino acid threonine for example (column 1 lines 58-60 the 4th amino acid) . Derynck is cited as evidence that the composition contains the amino acid threonine in the form of a protein. Thus the limitations of claims 1-4,15 of the instant invention are met.

'419 teach the TGF-beta at specific concentrations (claim 1 for example) meeting the limitations of claim 5 as currently interpreted.

Although unclear (see 112 2nd above) the claims have been interpreted broadly. In particular since the 'amounts' of claim 5 are unclear any composition including the recited component is interpreted as reading on the claim.

It is noted that claim 1, for example, recites that the composition is 'for restoring or promoting a healthy and optimal microbiota ecosytem'. However, the intended use recitation does not limit the claim to a particular structure (see MPEP 2111.04). Further, products of identical compositions can not have mutually exclusive properties (see MPEP 2112.01 II).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5,15 directed to an invention not patentably distinct from the claims of commonly assigned U.S. Patent No. 5,863,906, U.S. Patent No. 5,756,481, and copending Application No. 10/595,419 as discussed above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 5,863,906, U.S. Patent No. 5,756,481, and copending Application No. 10/595,419, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly

assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

The examiner has identified three copending Applications/patents which have been rejected under Double Patenting above. Because of Applicant's prolific Patent and Application portfolio, the burden is shifted to Applicant to identify all relevant Applications and Patents and to include said Applications and Patents on any terminal disclaimer filed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Dell et al., (US 4,491,589) teach amino acid solutions for example claims 7-19,21-22.

The above cited (double patenting section) U.S. Patent No. 5,756,481 and U.S. Patent No. 5,863,906 qualify as prior art. The above cited Shahjee et al. (J. Biosci. v27 Sept 2002 515-520) and Jacobson et al. (US 6,166,181) (101 rejection) qualify as prior art. Any rejections using these references would be duplicative of the rejections above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald T Niebauer/
Examiner, Art Unit 1654

/Anish Gupta/
Primary Examiner, Art Unit 1654